

## **REMARKS/ARGUMENTS**

Claims 6-9 remain in this application. For the reasons set forth below, it is submitted that claims 6-9 are in condition for allowance and allowance of the application is respectfully requested.

### **Rejections under 35 USC §102(e)**

In the Office Action, claim 6 was rejected under 35 U.S.C. §102(e) as being unpatentable over *Japuntich* (U.S. Pat. No. 5,695,489). For the reasons set forth below, Applicant respectfully traverses the rejection of claim 6 over the art and respectfully submits that claim 6 defines patentable subject matter over the prior art.

Claim 6 of the present invention recites a flexible plastic bag or reservoir for recirculation washing of blood cells which has a bottom inlet port and a top outlet port through which a less dense suspension of blood cells is withdrawn from the bag or reservoir for further processing. The flexible plastic bag or reservoir for recirculation washing of blood cells also includes an integral coarse filter comprising a tube of semi-rigid, non-collapsible plastic mesh extending from the top outlet port into the bag. Because the integral coarse filter is semi-rigid, it holds open a path through the otherwise collapsed bag or reservoir for the cells to move up to the top outlet port.

The location of the inlet and outlet ports of the present invention was designed to facilitate flow from bottom to top of the bag. In addition, as disclosed at paragraph [0019] of Applicant's published application,

"(u)se of a flexible recirculation wash bag with ports at the top and bottom and flow from bottom to top provides several advantages as compared to a bag with inlet and outlet ports at the bottom, as currently used on the Isolex.RTM. 300i. First, using a flexible bag allows the volume to be varied depending on the number of cells. Exiting from the top has the advantage of removing the less dense supernatant preferentially. This aids in making the concentration ratio high...For large volumes or slow flow rates, some sedimentation of the larger cells also aids in reducing the cell concentration at the outlet port. The system has the advantage of having the most washed and most concentrated cells at the bottom with the least washed and least concentrated cells at the top."

In contrast to the present invention, the *Japuntich* reference discloses a device for receiving, storing, filtering, and reinfusing a patient's blood. The device includes a

container (12) having an inlet port (14) to receive blood from a patient and a first outlet port (16) for reinfusing blood back into the patient (see Fig. 1). As disclosed at column 3, lines 51-54, "(i)n the preferred embodiment, the inlet port 14 is located along the *top* 50 of the container 12 and the outlet port 16 is located along the *bottom* of the container 12." (emphasis added) Moreover, all disclosed embodiments, as shown in Figures 1-7 of the *Japuntich* reference, include an inlet port located at the top of the container and an outlet port located at the bottom of the container.

The locations of the inlet and outlet ports of the *Japuntich* device were specifically designed to overcome problems associated with then-conventional blood filter bags. (see column 1, lines 41-51) For example, one problem frequently associated with filtering devices was that many "devices have both the inlet and outlet ports located at the same end of the collection container" which makes such devices "more difficult to use because they must be rotated 180 degrees prior to reinfusing blood back into a patient." (column 1, lines 41-48) To address this problem, the *Japuntich* device was designed so that "the inlet port 14 is located along the top 50 of the container 12 and the outlet port 16 is located along the bottom 52 of the container 12." (column 3, lines 52-54)

No where does the *Japuntich* reference disclose or suggest a device having an inlet port located at the bottom of the bag/reservoir and an outlet port located at the top of the bag/reservoir as in the presently claimed invention.

**Rejections under 35 USC §102(b)**

In the Office Action, claim 7 was rejected under 35 U.S.C. §102(b) as being anticipated by *Hauer et al.* (U.S. Pat. No. 4,443,220). For the reasons set forth below, Applicants respectfully traverse the rejection of claim 7 over the art and respectfully submit that the amended claim defines patentable subject matter over the prior art.

Claim 7 of the present invention recites a flexible plastic bag or reservoir for recirculation washing of blood cells which has a top outlet port and a bottom inlet port. In addition, the flexible plastic bag or reservoir for recirculation washing of blood cells also includes a bubble trap at the top, which comprises plastic tubing extending into the bag or reservoir from the top outlet port.

As detailed above, the location of the inlet and outlet ports of the present invention was designed to facilitate flow from bottom to top of the bag. In addition, as disclosed at paragraph [0019] of the Applicant's published application,

"(u)se of a flexible recirculation wash bag with ports at the top and bottom and flow from bottom to top provides several advantages as compared to a bag with inlet and outlet ports at the bottom, as currently used on the Isolex.RTM. 300i. First, using a flexible bag allows the volume to be varied depending on the number of cells. Exiting from the top has the advantage of removing the less dense supernatant preferentially. This aids in making the concentration ratio high...For large volumes or slow flow rates, some sedimentation of the larger cells also aids in reducing the cell concentration at the outlet port. The system has the advantage of having the most washed and most concentrated cells at the bottom with the least washed and least concentrated cells at the top."

In contrast to the present invention, the *Hauer et al.* reference discloses a device for the collection, temporary storage and transfer of whole blood to a patient. As disclosed in the specification and illustrated in 1, 2, 4 and 5, the device includes a collapsible collection bag (14) and a stent (16) that is assembled with the bag to hold it in distended form. The bottom of the bag has a pair of integrally molded tubes (25, 26) through which the contents of the bag may be transferred to a patient or to a receiving apparatus. (see column 2, lines 35-41) Two additional intake tubes (32, 34) are located near the top, with tube (32) acting as an air vent in certain procedures. (column 2, lines 44-61) Moreover, all disclosed embodiments of the *Hauer et al.* device include an intake tube/port located at the top of the container and an outlet port located at the bottom of the container.

As disclosed at column 3, lines 46-50, the *Hauer et al.* device was designed with a view to providing an improved apparatus for autotransfusion and "dealing with the problems of air emboli, poorly controlled anticoagulation and the need for sterility maintenance throughout the collection and reinfusion or other transfer phases." As such, for reinfusion of collected blood, the bag is suspended and "the blood is delivered to the patient by gravity." (see Figures 1-2 and column 4, lines 4-14)

This same configuration is utilized when the device is used as an on-line reservoir for a cell washing system. Referring to Figure 5 and as disclosed at column 4, lines 57-61, "(w)hen it is desired to drain blood from the bag to the cell washer, the

clamp is removed from the tube 90 and...blood then drains into the cell washer by gravity." Similarly, when the device is used as a cardiomy reservoir, the collected material inside the bag is "reinfused by gravity either directly to the patient or to a cell processing system." (column 5, lines 15-17)

The disclosed configurations of the *Hauer et al.* device and their associated methods of use including blood delivery to a patient/cell processing system by gravity limit the location of the outlet port to the bottom of the bag/container. As such, the *Hauer et al.* reference does not disclose or suggest a device having an inlet port located at the *bottom* of the bag/reservoir for receiving blood cells and an outlet port located at the *top* of the bag/reservoir for withdrawing blood cells as in the presently claimed invention.

**Rejections under 35 USC §103**

In the Office Action, claims 8-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Japuntich* in view of *Hauer et al.* Although the Examiner conceded that claims 8-9 essentially differ from the blood bag of *Japuntich* in reciting a bubble trap at the top comprising plastic tubing extending from the top port into the bag inside the mesh tube, the Examiner maintained that it would have been obvious to a person of ordinary skill in the art to modify the blood bag of *Japuntich* to incorporate a tube extending from the top port into the bag of *Japuntich* inside a mesh filter to remove air as suggested by *Hauer et al.* This rejection must fail for at least the same reasons as set forth in the traversal of claim 1 under 35 U.S.C. §102(e) above. In short, the *Japuntich* reference fails to disclose or suggest the elements of claim 8, namely, a device having an inlet port located at the *bottom* of the bag/reservoir and an outlet port located at the *top* of the bag/reservoir. As such, the *Japuntich* reference fails as a primary reference at the outset. In addition, although the *Hauer et al.* device includes an air vent (32), the air vent extends from the *top intake* port of the device. As such, *Hauer et al.* reference does not overcome the deficiencies of the *Japuntich* reference.

Therefore, at a minimum, neither the *Japuntich* patent nor the *Hauer et al.* patent, either alone or in combination, teach or suggest a device that includes a top port for withdrawing blood cells and a bottom port for receiving blood cells, nor do they disclose

a bubble trap/air vent that extends into the bag via the top outlet port. For the reasons stated above, it is respectfully submitted that claim 8 is not obvious over the *Japuntich* and *Hauer et al.* references. In addition, claim 9, which is dependent to claim 8, further distinguishes over the prior art and thus is independently patentable over claim 8.

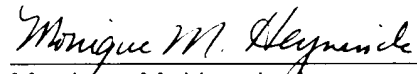
In view of the foregoing, it is submitted that all pending claims 6-9 are in condition for immediate allowance. Accordingly, Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

If for any reason direct communication with Applicant's attorney would serve to advance prosecution of this case to finality, the Examiner is cordially urged to call the undersigned attorney at the below listed telephone number.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-1329.

Respectfully submitted,  
STRADLING YOCCA CARLSON & RAUTH

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